

Message Text

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PAGE 01 STATE 148215
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-07 /023 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP:JFRY
DHEW/PHS/OASH/OIH: RBUHRICH,M.D.
EA/ANP:HTNELSON(INFO)

-----081405 242310Z /70

O 242244Z JUN 77

FM SECSTATE WASHDC
TO AMEMBASSY WELLINGTON IMMEDIATE

UNCLAS STATE 148215

E.O. 11652: N/A

TAGS: BEXP, TBIO, NZ

SUBJECT: INQUIRY FROM GNZ CONCERNING FDA TESTS

REF: WELLINGTON 2000

1. FDA ADVISES THAT IT HAS NO REPEAT NO DEFINITION FOR
ULTRA-SOFT CONTACT LENS. NO LENS BY NAME ULTRA SOFT HAS
BEEN SUBMITTED AS IND (INVESTIGATIONAL NEW DRUG) NOR
APPROVED BY FDA. AGENCY HAS REVIEWED ONLY HARD (REGULATED
AS MEDICAL DEVICE) AND SOFT (REGULATED AS "NEW DRUG")
CONTACT LENSES.

2. FDA REQUESTS FOLLOWING:

- (A) NAME OF COMPOUND AND/OR POLYMER USED TO FORM LENS.
- (B) NAME OF FIRM WHO SUBMITTED APPLICATION TO GNZ.
- (C) NAME AND FORMULATION OF CHEMICAL SOLUTION TO BE USED
N STERILIZATION OF LENS.
- (D) IF LENS CAN BE DISINFECTED BY HEAT WHICH UNIT WOULD

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BE USED?

3. FDA REGRETS DELAY IN REPLYING TO EMBASSY INQUIRY. CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT
Control Number: n/a
Copy: SINGLE
Sent Date: 24-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Executive Order: N/A
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Expiration:
Film Number: D770227-0425
Format: TEL
From: STATE
Handling Restrictions: n/a
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ISecure: 1
Legacy Key: link1977/newtext/t19770619/aaaaaqom.tel
Line Count: 58
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 63de7e76-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
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Previous Handling Restrictions: n/a
Reference: 77 WELLINGTON 2000
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 08-Nov-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2033818
Secure: OPEN
Status: NATIVE
Subject: INQUIRY FROM GNZ CONCERNING FDA TESTS
TAGS: BEXP, TBIO, NZ, FDA
To: WELLINGTON
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/63de7e76-c288-dd11-92da-001cc4696bcc
Review Markings:
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